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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LIU, SAMUEL W	

ART UNIT	PAPER NUMBER
1653	13

DATE MAILED: 08/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/930,329	TURPEN, THOMAS H.	
	Examiner	Art Unit	
	Samuel W Liu	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2003 and 19 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-35* is/are pending in the application.

4a) Of the above claim(s) *none* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-35* is/are rejected.

7)☒ Claim(s) *26* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicants' preliminary amendment filed 8 January 2002 (Paper No. 5) as to cancellation of claims 1-11 and 14-25 and amendment of claims 12-13, and amendment filed 19 February 2003 (Paper No.10) as to cancellation of claims 12-13 and addition of claims 26-35 have been entered. Thus, the pending claims 26-35 are under examination to the extent that they are drawn to the elected invention.

IDS

Please note that Applicants' submission of IDS filed 8 July 2002 (Paper No. 6) is incomplete since it contains no copies of each U.S. and foreign patent and each publication or that portion, which caused it to be listed as cited in the list of the submitted IDS. Thus, it fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C (1). Yet, examiner has reviewed US patent document of IDS (US Pat. NO. 5965794).

Specification/Claims Objections

The disclosure is objected to because of the following informalities:

In page 6, line 12, "30-kDa" should be changed to "30 KDa". See also page 20, line 22.

In page 16, line 12, "CSF-G", "CSF-GM" and "CSF-M" should be fully spelled out for the first instance of use.

In claim 26, after "a host RNA polymerase" the coma "," should be deleted.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, the first paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 29 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of a method of over expressing genes in plant comprising a replicon having chimeric multicistronic gene under control by a plant promoter, a viral replication origins, and a viral sequence encoding a functional movement protein allowing systemic infection of the plant and systemic expression of the gene(s) thereby amplifying expression of interest product, in the presence of a helper virus using conventional recombinant technology.

Applicant is not in possession of a method stated above involving a self-cleaving mRNA that is generated forth the method above because the instant specification provides insufficient description or/and guidance as to how the self-cleavage mechanism has an input on the claimed method. Further, the specification fails to describe additional representative example or any other evidence of record which shows the self-cleavage is particular important or useful in plant plus-strand RNA-virus based over expression of foreign genes encoding *antisense*

polynucleotide, or *ribozyme RNA*, or regulatory enzymes, or structural, regulatory and therapeutic proteins. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus. *See University of California v. Eli Lilly and co. 43 USPQ2d 1398.*

Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Claim Rejections - 35 USC § 112, the second paragraph

Claims 26-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 recites "a plus sense" (lines 3, 7 and 11 of the claim); the recitation is not apparent as to whether or not the said plus strand refers to DNA or RNA. Also, claim 26 is indefinite in the recitation "replicating the recombinant mRNAs with the plus sense, RNA viral replicase, thereby producing additional replicon components" because it is unclear as to whether or not RNA replicase also participates in said "replicating" event and as to what are components additional to the recombinant mRNA molecules and the replication origin. The dependent claims are also rejected.

Claim 29 recites "producing the subgenomic mRNA further comprises self-cleaving the mRNA"; the recitation is not apparent as to how to produce mRNA via self-cleavage; is the self-

cleavage mechanism is specific for producing ribozyme or antisense polynucleotide? does the said mRNA contain *cis* - ribozyme-like component?

Claim 30 recites "producing the subgenomic mRNA further comprising translating the mRNA"; the recitation is not apparent as to how the mRNA translation produces the said mRNA molecules. Note that claim 26 from which claim 30 depends sets forth at least two different steps: producing the mRNA and expressing the gene by translating the mRNA.

Claim 34 is indefinite because it is unclear as to how many sequences there are encoding the functional movement protein.

Claim Rejection –Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Claims 26-28 and 30-35 are rejected under the judicially created doctrine of the obviousness-type double patenting of claims 16-20 of US Pat. No. 5811653. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 16-20 of 5811653 and claims 26, 28 and 30 of the instant application disclose the common subject matter, i.e., a method of expressing a foreign product in plants comprising (a)

integrating a transgene into a chromosome of a plant cell for transcribing the transgene comprising a replicon which comprises: a TMV-derived *replication origin* for replicating the replicon, and a foreign polynucleotide sequence (see claim 17), a helper virus (note that tobamovirus (TMV) is a single RNA virus wherein the RNA is plus strand RNA (see column 2, lines 41-42), and that the replicon is a RNA sequence generated from transcribing the transgene (see column 5, lines 59-65) with host RNA polymerase II (see column 7, lines 10-12)); (b) providing the plant cell with the a TMV-derived helper virus comprising a gene encoding a TMV-derived *replicase* that is necessary for the replicon function *via* infecting the plant with the helper virus; and (c) producing the additional replicon component, i.e., the movement protein via translating the mRNA (i.e., the component of the replicon that is of RNA sequence) that directs synthesis of the movement protein (see the patent claim 16 and 18-20). The above disclosure of 5811653 meets all the limitation set forth in the application claims 26, 28 and 30. Since claim 16 also sets forth the transected plant cell is suspectable to the tobamovirus for producing gene product, i.e., the functional movement protein, which meets the limitation of the instant claim 35, claims 16 and 18-20 of 5811653 are obvious variation of claims 26, 28, 30 and 35 of the current application.

Claim 16 of 5811653 sets forth a method for introducing the transgene into the subject plant wherein introducing the transgene is done by known transformation (see column 7, line 38) with growing the subject plant to an optimal condition prior to introducing the helper virus (see also column 7, lines 42-44). Thus, claim 11 of patent 5811653 is an obvious variation over claim 27 of the instant application.

Also, claim 16 of 5811653 is an obvious variation over claims 31-32 of the instant application since the claimed invention of 5811653 is directed to the method of over expressing genes in plant (see abstract) wherein the gene products include antisense RNA, ribozyme RNA, regulatory enzyme, structural protein, regulatory protein, or therapeutic protein wherein typical therapeutic proteins include members of the interleukin family of proteins and colony stimulating factors (see also column 7, lines 45-49).

Claims 16 and 18-20 of 5811653 disclose a functional movement protein encoded by the sequence of the replicon upon which the helper virus depends (see also column 6, lines 55-58), which is the common subject matter set forth in claim 33 of the current application.

Further, claim 16 of 5811653 sets forth the replicon encodes the functional movement protein for which the helper virus does not encode and the function of the helper virus depends on the movement protein (see also column 6, lines 55-65 of 5811653), and because the invention of 5811653 is directed to the method for systemically infect a plant and systematically amplifying expression of the interest product (see the patent abstract and column 13, lines 37-38). Thus, claim 16 is an obvious variation over the instant claim 34.

Therefore, the claims stated above in the instant application and those in US Pat. No. 5811653 discloses the same and/or common subject matter.

Claims 26-28 and 30-35 are rejected under the judicially created doctrine of the obviousness-type double patenting of claims 10-12 of US Pat. No. 5889191. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 10 of 5889191 and claims 26 and 28 of the instant application disclose the common subject matter, i.e., a method of expressing a foreign product in plants comprising (a) integrating a transgene into a chromosome of a plant cell for transcribing the transgene comprising a replicon which comprises: a plus strand RNA plant virus-derived *replication origin* for replicating the replicon, and at least one foreign polynucleotide sequence (non-native to the plus strand RNA), a helper virus (note that the replicon is a RNA sequence generated from transcribing the transgene (see column 5, lines 57-62) with host RNA polymerase II (see column 7, lines 7-8); (b) providing the plant cell with the a helper virus comprising a gene encoding a plant RNA virus *replicase* that is necessary for the replicon function *via* infecting the plant with the helper virus; and (c) producing the additional replicon component, i.e., the movement protein via translating the mRNA (i.e., the component of the replicon that is of RNA sequence) that directs synthesis of the movement protein. The above disclosure of 5889191 meets all the limitation set forth in the application claims 26, 28 and 30. Claims 11-12 of 5889191 also sets forth the transected plant cell is comparable to the tobamovirus (TMV) for producing gene product, i.e., the functional movement protein, which meets the limitation of the instant claim 35. Thus, claims 10-12 of 5889191 are obvious variation of claims 26, 28, 30 and 35 of the current application.

Claim 10 of 5889191 sets forth a method for introducing the transgene into the subject plant via transformation wherein introducing the transgene is done by known transformation (see column 7, line 34) with growing the subject plant to an optimal condition prior to introducing the helper virus (see also column 7, lines 36-39). Thus, claim 10 of patent 5889191 is an obvious variation over claim 27 of the instant application.

Claim 10 of 5889191 is an obvious variation over claims 31-32 of the instant application since the claimed invention of 5889191 is directed to the method of over expressing gene products in plants which include antisense RNA, ribozyme RNA, regulatory enzyme, structural protein, regulatory protein, or therapeutic protein wherein typical therapeutic proteins include members of the interleukin family of proteins and colony stimulating factors (see also column 7, lines 41-50).

Claims 10-11 of 5889191 disclose a functional movement protein encoded by the sequence of the replicon upon which the helper virus depends (see also column 6, lines52-54), which is the common subject matter set forth in claim 33 of the current application.

Claims 10-12 of 5889191 are obvious variations over claims 33-34 of the instant application because claims 10-11 of 5881919 sets forth the replicon encodes the functional movement protein which the helper virus does not encode (see claim 10) and the function of the helper virus depends on the movement protein (see also column 6, lines 52-54), and because 5889191 invention is directed to the method for systemic infection of subject plant and systemic expression of the gene product (see the patent abstract and column 15, lines 10-12).

Therefore, the claims stated above in the instant application and those in US Pat. No. 5889191 discloses the same and/or common subject matter.

Claims 26-28 and 30-35 are rejected under the judicially created doctrine of the obviousness-type double patenting of claims 13-19 of US Pat. No. 6462255. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 13-17 of 6462255 and the instant claims 26, 28 and 30 discloses the common subject matter, i.e., a method of expressing a foreign product in plants comprising (a) integrating a transgene into a chromosome of a plant cell for transcribing the transgene comprising a replicon which comprises: a plus strand RNA plant virus-derived *replication origin* for replicating the replicon, and at least one foreign polynucleotide sequence (non-native to the plus strand RNA), a helper virus (note that the replicon is a RNA sequence generated from transcribing the transgene (see column 6, lines 10-15) with host RNA polymerase II (see column 7, lines 25-27); (b) providing the plant cell with the a helper virus comprising a gene encoding a TMV-derived *replicase* that is necessary for the replicon function (see claim 21) *via* infecting the plant with the helper virus; and (c) producing the additional replicon component, i.e., the movement protein via translating the mRNA (i.e., the component of the replicon that is of RNA sequence) that directs synthesis of the movement protein. The above disclosure of 6462255 meets all the limitation set forth in the application claims 26, 28 and 30. Claims 18-19 of 6462255 sets forth the transected plant cell is susceptible to the tobamovirus (TMV) for producing gene product, i.e., the movement protein, which meets the limitation of the instant claim 35. Thus, claims 13-19 6462255 are obvious variation of claims 26, 28, 30 and 35 of the current application.

Claim 13 of 6462255 sets forth a method for introducing the transgene into the subject plant wherein introducing the transgene is done by known transformation (see column 7, line 54) with growing the subject plant to an optimal condition prior to introducing the helper virus (see also column 7, lines 54-59). Thus, claim 10 of patent 6462255 is an obvious variation over the instant claim 27.

Claim 10 of 6462255 is an obvious variation over claims 31-32 of the instant application since the claimed invention of 6462255 is directed to the method of over expressing gene products in plants which include antisense RNA, ribozyme RNA, regulatory enzyme, structural protein, regulatory protein, or therapeutic protein wherein typical therapeutic proteins include members of the interleukin family of proteins and colony stimulating factors (see also column 7, lines 60-67).

Claims 13-19 of 646255 disclose the functional movement protein encoded by the sequence of the replicon upon which the helper virus depends (see also the patent claims 4-5), which is the common subject matter set forth in claim 33 of the current application.

Claims 14 and 15 of 6462255 are obvious variations over claim 34 of the instant application because claim 14 discloses that the helper virus depends upon the replicon and claims 15 sets froth that the function of the helper virus depends *in trans* on expression of functional movement protein encoded by the replicon which causes systemic expression of said replicon (see the patent claims 1 and 7). Note that the method the patent claims 13-19 disclose the replicon which properties and biological functions are described in the patent claim 1 and 7.

Therefore, the claims stated above in the instant application and those in US Pat. No. 6462255 discloses the same and/or common subject matter.

Claims 26-28 and 30-35 are rejected under the judicially created doctrine of the obviousness-type double patenting of claims 11-16 of US Pat. No. 5965794. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 26, 28 and 30 of the instant application and claims 11-14 of 5965794 disclose the common subject matter, i.e., a method of expressing a foreign product in plants comprising (a) integrating a transgene into a chromosome of a plant cell for transcribing the transgene comprising a replicon which comprises: a plus strand RNA plant virus-derived *replication origin* for replicating the replicon, and at least one foreign polynucleotide sequence (non-native to the plus strand RNA), a helper virus (note that the replicon is a RNA sequence generated from transcribing the transgene (see column 6, lines 4-9) with host RNA polymerase II (see column 7, lines 22-23); (b) providing the plant cell with the a helper virus comprising a gene encoding a TMV-derived *replicase* that is necessary for the replicon function *via* infecting the plant with the helper virus; and (c) producing the additional replicon component, i.e., the movement protein via translating the mRNA (i.e., the component of the replicon that is of RNA sequence) that directs synthesis of the movement protein. The above disclosure of 5965794 meets all the limitation set forth in the application claims 26, 28 and 30. Claims 12-16 of 5965794 sets forth the transected plant cell is suspectable to the tobamovirus (TMV) for producing gene product, i.e., the movement protein, which meets the limitation of the instant claim 35. Thus, claims 11-16 of 5965794 are obvious variation over the instant claims 26, 28, 30 and 35 of the current application.

Claim 11 of 5965794 sets forth a method for introducing the transgene into the subject plant wherein introducing the transgene is done by known transformation (see column 7, line 50) with growing the subject plant to an optimal condition prior to introducing the helper virus (see also column 7, lines 51-55). Thus, claim 11 of patent 6462255 is an obvious variation over the instant claim 27.

Claims 11 and 14 of 5965794 are obvious variation over claims 31-32 of the instant application since the invention of 5965794 is directed to the method of over expressing gene products in plants which include antisense RNA, ribozyme RNA, regulatory enzyme, structural protein, regulatory protein, or therapeutic protein wherein typical therapeutic proteins include members of the interleukin family of proteins and colony stimulating factors (see also column 7, lines 56-63).

Claims 11-16 of 5865794 disclose a functional movement protein encode by the sequence of the replicon upon which the helper virus depends (see also column 5, lines 26-28), which is the common subject matter set forth in claim 33 of the current application.

Claims 11 and 14 of 5965794 are obvious variations over claim 34 of the instant application because claim 11 and 14 disclose that the helper virus depends upon the replicon and that the replicon encodes the movement protein which causes systemic expression of said replicon (see the patent claim 7 and abstract), which meets the limitation set forth in instant claim 34.

Therefore, the claims stated above in the instant application and those in US Pat. No. 5965794 discloses the same and/or common subject matter.

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. The terminal disclaimers signed by the assignee must fully comply with 37 CFR 3.73(b) with respect to the above rejections.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is (703) 306-3483. The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low, can be reached on 703 308-2923. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

SWL

Samuel W. Liu, Ph.D.

August 15, 2003

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER